

AWARD NUMBER: W81XWH-15-1-0417

TITLE: Sensory Feedback for Lower Extremity Prostheses Incorporating
Targeted Muscle Reinnervation (TMR)

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14. ABSTRACT The purpose of this research is to improve stair descent for lower limb amputees by providing sensory feedback of foot placement. An increasing number of amputees are receiving a nerve transfer surgery, Targeted Reinnervation, that can have profound sensory effects. Touches at the site of the surgery can feel like they are originating from the amputated limb. This capability is an unprecedented opportunity to provide sensory feedback that is intuitive and useful, but sensory recovery after the surgery is not well understood. Therefore the two Specific Aims of this project are to (1) Systematically map and characterize the sensory capabilities of lower extremity Targeted Reinnervation (TR) sites under tactile stimulation, and (2) Measure the effects of vibrotactile cues of foot placement on stair descent of transtibial amputees. We have created the tactile stimulation apparatus and protocols for both of these aims, including a novel stimulator design and a novel methodology for understanding visual-tactile integration. We have recruited all personnel, received approval to conduct the studies, pending final review by HRPO, and have conducted preliminary studies using control participants for the already-approved sensory studies.					
15. SUBJECT TERMS Prosthetic Limb, Lower Extremity, Mobility, Locomotion, Stair, Sensory Replacement, Sensory Feedback, Vibrotactile, Haptic, Psychophysics, Targeted Reinnervation, Targeted Muscle Reinnervation, Targeted Sensory Reinnervation					
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Introduction

We seek to improve stair descent for lower limb amputees by providing sensory feedback of foot placement. An increasing number of amputees are receiving a nerve transfer surgery, Targeted Reinnervation, that can have profound sensory effects. Touches at the site of the surgery can feel like they are originating from the amputated limb. This capability is an unprecedented opportunity to provide sensory feedback that is intuitive and useful, but sensory recovery after the surgery is not well understood.

Therefore the two Specific Aims of this project are to (1) Systematically map and characterize the sensory capabilities of lower extremity Targeted Reinnervation (TR) sites under tactile stimulation, and (2) Measure the effects of vibrotactile cues of foot placement on stair descent of transtibial amputees.

In this first year we have taken the first steps toward these aims.

Keywords

Prosthetic Limb, Lower Extremity, Mobility, Locomotion, Stair, Sensory Replacement, Sensory Feedback, Vibrotactile, Haptic, Psychophysics, Targeted Reinnervation, Targeted Muscle Reinnervation, Targeted Sensory Reinnervation

Accomplishments

What are the major goals of the project?

Specific Aim 1 is to systematically map and characterize the sensory capabilities of lower extremity Targeted Reinnervation (TR) sites under tactile stimulation. This aim is divided into two Major Tasks:

Major Task 1: Development of Lower-Limb Vibrotactile Stimulation Technologies

We are developing devices and techniques for tactile stimulation of the residual limb for amputees who have not had TR, and the TR surgery site for those who have.

There are two main technologies under development for assessing sensory capabilities. The first technology (Figure 1) is a single stimulator that can precisely measure and control the force applied, as well as the movement frequency and linear displacement of the skin-tactor interface. The design incorporates two major elements – a constant-force sliding handle, and an effector that can be either conventional stimulators, or the cam-follower vibrotactor design pictured in Figure 2. The cam-follower design allows the frequency to be set by commands to a motor, and the amplitude to be specified by the profile of the cam. Conventional vibrotactors do not allow this free setting of both parameters, and are wider and flatter, which reduces the maximum resolution of an array of tightly placed tactors.

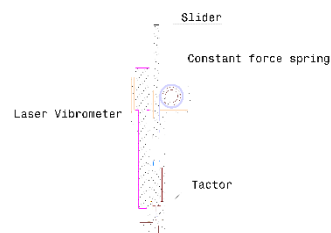


Figure 1: Tactile stimulation wand. The design allows for careful measurement and control of force and frequency.

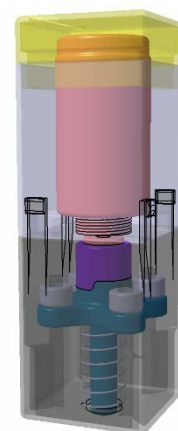


Figure 2: The cam-follower vibrotactor enables a higher-resolution tactile display than standard vibrotactors.

The second technology is an array of stimulators. This allows different places on the skin to be stimulated without manually moving the tactor, and will also be used in Specific Aim 2, when delivering the tactile feedback of foot placement. We are focusing on two prototype designs for this technology, one based on the novel cam-follower vibrotactor, and the other using piezoelectric vibrotactors (Figure 3).

We are also developing two techniques for assessing sensory capabilities. The first is a protocol of stimulation and a touch-screen program used by the participant to indicate the felt sensations. The protocol is based on standard psychophysical experimental technique, wherein a stimulation, from either monofilaments or vibrotactors, is repeated at the same intensity for two out of three touches. The participant indicates whether and where the sensation was felt using the computer program (see Figure 4). Correct “whether” answers are used to measure minimum perceivable stimulation intensity thresholds, and “where” answers are used to map the touched locations to perceived locations. This protocol has been conducted for participants without amputation to establish baselines and guide development.

The second technique makes use of Virtual Reality (VR) to provide visual and tactile touch stimulation, as depicted in Figure 5. This system provides full control over the visual experience, by changing the virtual body and virtual world. This allows us to understand how multisensory experiences of vision and tactition are combined to create useful sensations. By depicting an intact limb “in virtuo” to the participants with amputation and who have had TR surgery, we are able to systematically vary stimulation parameters and collect quantitative behavioral responses.

Major Task 2: Mapping and characterization studies of targeted reinnervation (TR) sites

This second major task for Specific Aim 1 is to conduct the sensory studies using the developed apparatus and techniques. Firstly, we have designed the studies and obtained local Veterans Affairs Institutional Review Board (IRB) and Human Research Protection Office (HRPO) approval to conduct them. IRB approval within the VA is more elaborate than within the university setting, and our center has dedicated staff to facilitate approval. We submitted an initial protocol for review that included only the sensory mapping and characterization (not the stair descent) on 3/19/2015 and received local IRB

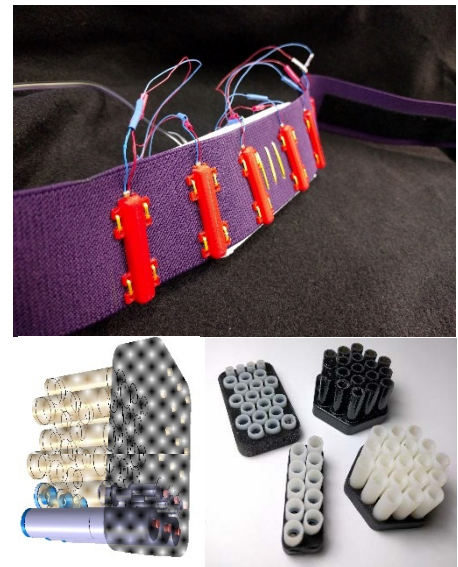


Figure 3: Above: Array of piezoelectric vibrotactors, under custom skin interface enclosures. The strap affixes the array to the thigh, outside of the socket. Below: High-resolution arrays of tactors.



Figure 4: Touch-screen program for indicating perceived touches.

IRB SUBMISSION TRACKING LOG

Investigator: Eric Rombokas, PhD
Study Site: Seattle VA

MIRB #: 00807
Sponsor: Dept of Defense

*Retain complete copies of all items submitted or received pertaining to the submission

Reason for Submission / Document(s) Submitted*	Date Submitted to IRB	Date IRB/R&D Approved	Date Returned	Approval Letter(s) in files	Comments
IRQ and R&D application	3/19/2015	5/12/2015	5/27/2015	yes	
HRPO/DoD application	6/3/2015	10/13/2015	10/13/2015	Yes	Initial review packet; approval forwarded to VA IRB 10/14/15
PRAF 1	1/18/2016	1/21/2016	1/27/2016	Yes	Add UW IRB to consent form (now on V2 1/15/2016) and HIPAA form (now on V2; 1/15/2016)
CRQ 2016	2/17/2016	3/16/2016	3/22/2016	Yes	Emailed a copy of submission packet and approval letters to PI to send to DoD from his UW email (VA email down 3/22/2016)
HRPO/DoD CRQ	3/24/2016	N/A	5/20/2016	Yes	Emailed copy of CRQ packet and approval to HRPO; had to resubmit on 3/28/16
Study Staff Update	7/14/2016	7/14/2016	7/14/2016	Yes	remove Vijeth Rai, add Lalit Palve, David Caballero, and Astrini Sie
PRAF 2	9/28/2016	10/12/2016	10/13/2016	Yes	add stair procedures, complete study protocol, add pilot study component; revise recruitment/screening materials, consent form, HIPAA, variable list
HRPO/DoD PRAF 2	10/14/2016				Sent via gmail – attachment too large for VA email

Table 1: Human subjects research oversight submissions and approvals

approval on 5/12/2015. We received HRPO approval four months later. The protocol was updated to include stair descent, approved 10/12/2016 by local IRB and pending approval by HRPO. In summary, we are ready, in technology, protocols, and institutional hurdles, to recruit participants with amputation and the targeted reinnervation surgery as soon as we receive approval from HRPO.

Mapping and characterization studies have been tuned and have begun for two control subjects having no amputation. Based on these experiments we are ready to begin recruitment of amputees with and without the nerve transfer surgery. Light touch monofilament experiments have established a baseline for accuracy and variance of touch perception for relevant anatomical points. A representative example, including the touch-screen GUI, is shown in Figure 4. We have also found that simultaneous visuo-tactile experience of touch on the upper leg is surprisingly insensitive to mismatch between the location of real-world tactile touch and the location of the apparent visual touch. We placed participants (with no amputation) in a virtual seated position, with the avatar's leg matching the dimensions and orientation of their real-world leg. A virtual wand appeared visually to touch the leg, while the real-world wand provided tactile touch, but offset by varying degree. Figure 7 shows the average confidence that the vision matched the tactile sensation, as a function of offset. Even with 6 centimeters difference between visual and tactile stimulation, subjects responded positively about half the time, indicating a unified perceptual experience of a single touch. This technique will be used to understand and numerically quantify the sensory capabilities and the mapping from visual and tactile touch stimuli to the resultant perceived touches.

Specific Aim 2 is to determine the effects of vibrotactile cues of foot placement on stair descent of transtibial amputees. This aim consists of two Major Tasks:

Major Task 3 is the development of a speed-adapting stair descent machine. This device is based on a commercially available stair exercise product, but modified to operate in descent mode (opposite the normal direction of an exercise stairmill) and to sense the location of the user in order to adapt the speed of operation. The commercially available device normally uses electromechanical resistance via a transmission system to the steps, intended for use in stair ascent. Our design calls for replacing the alternator with a powered motor for reverse operation (Figure 7). We are now developing embedded systems for integrating the motor driver with a system for tracking the user and computing an appropriate control for speed adaptation. We are also beginning construction of safety features such as emergency stop, platforms and handrails.

Major Task 4: Functional study of feedback for stair descent. Functional “dress rehearsal” tests have been conducted for real-time feedback system using an insole affixed to a medical boot. This allows testing with people without amputation, but simulates the lack of ankle dorsiflexion and tactile sensation that contribute to difficulty in stair descent. The insole is instrumented with force sensors linearly spaced heel to toe (Figure 8). We have developed two stimulation paradigms, consisting of a straight “sensory pass-through” where sensor activity is rendered faithfully to the tactors and “placement indicator” where sensor data is used to determine stair edge location and that alone is rendered to the tactors. Pending final approval formal recruitment will begin, using fixed stairs and steps. After speed adapting treadmill is completed it will be incorporated, and is already part of the IRB approval.

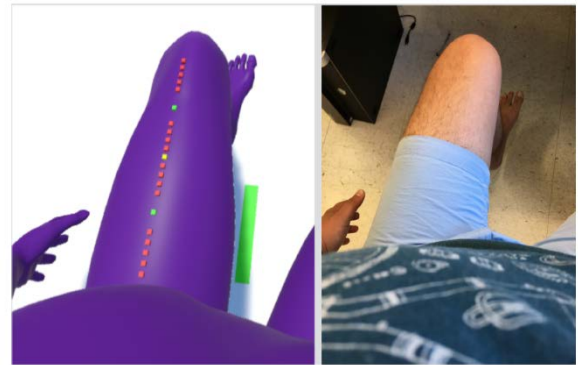


Figure 5: Participant's point of view in VR (left) and real world (right)

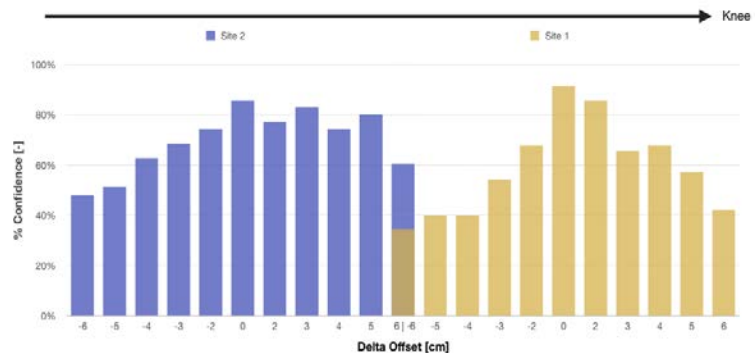


Figure 6: Confidence for offsets presented to Site 1 (closest to the knee) on the right in blue, and Site 2 to the left in yellow.

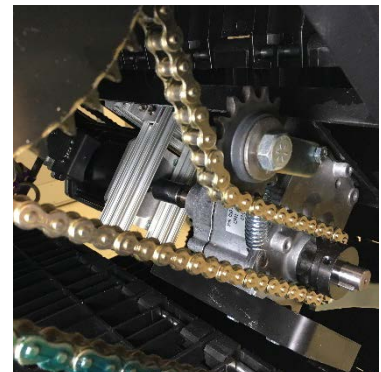


Figure 7: Stair Descent Machine. We have replaced the resistive alternator with a powered motor for reverse direction operation.

Opportunities for training and dissemination of results

The activities in this report are broad and interdisciplinary. Research assistants from Depts. Of Mechanical and Electrical engineering have spent extensive time working with the investigators to achieve these technological and methodological goals. Three presentations were given at the Northwest Biomechanics Symposium 2016, and four manuscripts are in preparation to disseminate the results of these efforts. We also occupied a booth for the University of Washington Engineering Discovery Days, which is an outreach event for middle school to high school students, in which we demonstrated the prostheses, sensors, and tactors, and described the research.

Plans for next reporting period

The immediate next phase of this research is to recruit a cohort of participants for the full study, including sensory characterization and mapping, to step tests with the tactors, to full stair ambulation. Particular effort will be made to establish best practices for delivering tactile stimulation appropriately to TR recipients based on the sensory characterization.

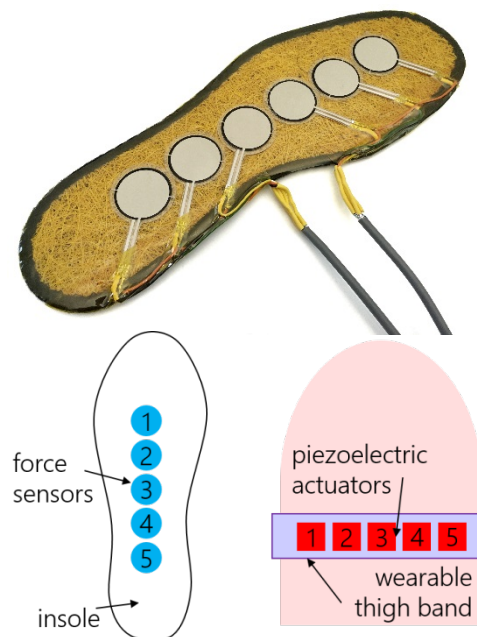


Figure 8: Foot placement sensory feedback scheme. The insole is pictured with exposed sensors but they are typically embedded inside. The wearable tactors are pictured in Figure 3.

Impact

Impact on the principal discipline of the project

We have conducted the first “visuo tactile two-point discrimination test.” In the study of tactile sensory capabilities, a common test is to see how close two touches must be before they feel like only one touch. Using the virtual reality setup (see Figure 5) we have created an equivalent multisensory test, to understand how vision and tactile sensation combine into a unified feeling. We anticipate this sort of multisensory study to become more important as we increasingly use mechanical devices, like powered prosthetic limbs that provide sensory feedback, as a part of our bodies. Finally, we anticipate the TR sensory mapping and characterization study to provide a valuable first look at the sensory consequences of lower extremity TR, and also the first to follow recipients longitudinally for months as they recover after surgery.

Impact on other disciplines

Nothing to report.

Impact on technology transfer

Though it remains early, we anticipate that the novel tactor designs will yield eventual commercial or clinical devices.

Impact on society

Nothing to report.

Changes / Problems

Changes in approach

Nothing to report.

Problems or delays

We have a complex experimental protocol that has taken us longer than we would like to have approved by IRBs and HRPO (about 125% of expected time). These approvals are now in place, except final review by HRPO, and we do not anticipate further action for resolution.

Impacts on expenditures

Funding for the project was received too late to recruit research assistants for the normal academic year, so they were recruited in winter instead of fall. Therefore there is an underexpenditure on head count for the first year. At this time the project is fully staffed and we intend to use these funds as needed to support further personnel for the remainder of the project period.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, or select agents

Nothing to report.

Products

Publications, conference papers, and presentations

Three presentations were given at the Northwest Biomechanics Symposium 2016

Technologies or techniques

We have pioneered a VR multisensory fusion protocol that we will be disseminating after further experimentation. We are also designing a variety of potentially impactful mechanical designs for tactile stimulators.

Participants and Other Collaborating Organizations

Name:	<i>Eric Rombokas</i>
Project Role:	<i>PI</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>2.4</i>
Contribution to Project:	<i>Oversight of all activities</i>
Funding Support:	<i>VA</i>
Name:	<i>Blake Hannaford</i>
Project Role:	<i>Co-I</i>
Researcher Identifier (e.g. ORCID ID):	

Nearest person month worked:	1.8
Contribution to Project:	<i>Oversight of development of tactile technologies and protocols</i>
Funding Support:	
Name:	Janna Friedly
Project Role:	Co-I
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1.2
Contribution to Project:	<i>Consideration of amputee and TR issues in design</i>
Funding Support:	
Name:	Jason Ko
Project Role:	Co-I
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1.2
Contribution to Project:	<i>Consideration of TR issues in design</i>
Funding Support:	
Name:	Lalit Palve
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6
Contribution to Project:	<i>Stimulation protocols and tactor design</i>
Funding Support:	
Name:	Huiwen Guo
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	4
Contribution to Project:	<i>Speed adapting stair descent machine development</i>
Funding Support:	
Name:	Astrini Sie
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	5
Contribution to Project:	<i>Stair protocols, tactor array design, stimulation paradigms</i>
Funding Support:	

Name:	<i>David Caballero</i>
Project Role:	<i>Research Assistant</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>5</i>
Contribution to Project:	<i>VR sensory protocol and apparatus</i>
Funding Support:	

Changes in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period

Nothing to report.

Other organizations involved as partners

University of Washington

Seattle, WA

Collaboration, Personnel Exchanges

Harborview Medical Center

Seattle, WA

Collaboration

Special Reporting Requirements

Quad chart

See attachments

Appendices

None

Sensory Feedback for Lower Extremity Incorporating TMR

MR140172 Neuromusculoskeletal Injuries Research Award

Funding Opportunity Number: W81XWH-14-DMRDP-CRMRP-NMSIR



PI: Eric Rombokas

Org: Seattle Institute for Biomedical and Clinical Research **Award Amount:** 1.5M

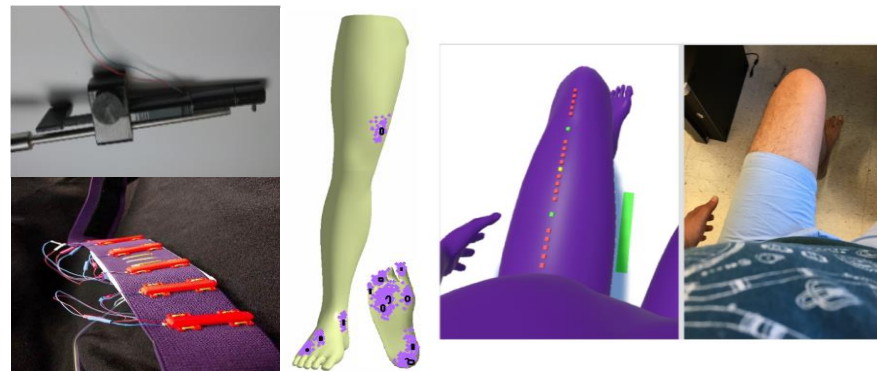
Study Aims

- **Map and characterize the sensory capabilities of lower extremity Targeted Reinnervation (TR) sites under vibrotactile stimulation.**
- **Measure the effects of vibrotactile cues of foot placement on stair descent of transtibial amputees.**

Approach

Assess sensory consequences of TR in lower extremity via Semmes-Weinstein monofilament exam, then use hand-held vibrotactile stimulator to measure for the vibrotactile haptic modality that would actually be used in an integrated sensorized prosthetic system.

Measure the effects of providing vibrotactile feedback of foot placement on self-selected speed of transtibial amputees performing stair descent. Subjects will descend integrated motion-capture speed-adaptive escalator.



Vibrotactor single stimulator (left, top) and worn array (left, bottom). Vibrotactile sensory feedback can deliver sensation of forces and foot events to the lower extremity amputee. Users having targeted reinnervation feel these sensations as if they are originating at the absent limb. Participants indicate where they felt sensations (middle). Sensory characterization is also performed by providing simultaneous visual and tactile sensation (right).

Timeline and Cost

Activities	CY	16	17	18	19
Develop Vibrotactile Actuators		<div><div></div></div>			
Develop automatic stair machine		<div><div></div></div>			
Sensory mapping of TR sites		<div><div></div></div>			
Stair Descent with feedback		<div><div></div></div>			
Estimated Budget (\$K)		\$496	\$498	\$497	\$000

Goals/Milestones

- Speed-adapting stairmill user tracking complete
- Final HRPO approvals for stair descent protocol

CY16 Goals –

- Functionality and safety tests of integrated motion capture stair machine
- Functionality tests of Handheld Feedback Wand and Wearable Feedback Array
- Sensory Mapping / Characterization and Stair Descent
- Gait lab tests of stair descent for amputees without TR surgery
- Characterization of TR site sensory capabilities